



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 25 2002

Jonathan W. Emord, Esq.
Emord and Associates, P.C.
5282 Lyngate Court
Burke, VA 22015

RE: Health Claim Petition – Selenium and Reduction in the Risk of Certain Cancers;
Selenium and Anticarcinogenic Effects.

Dear Mr. Emord:

This letter acknowledges receipt on July 10, 2001 by the Food and Drug Administration (FDA) of the petition you submitted, on behalf of Wellness Lifestyles, Inc., pursuant to Section 403(r)(5)(D) of the Federal Food, Drug and Cosmetic Act (FFD&C Act) (21 U.S.C. § 343(r)(5)(D)). The petition requests FDA authorization of health claims for use on the labels and in labeling of dietary supplements for the relationship between selenium and reduction in the risk of certain cancers and between selenium and anticarcinogenic effects.

This petition is undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the FFD&C Act and 21 CFR 101.70(j)(2), within 100 days of receipt of your petition, you will be notified of FDA's decision to either file the petition for comprehensive review, or to deny the petition. A denial may be by FDA action within the initial 100-day period, which ends on October 18, 2002, or by operation of law.

Please feel free to contact me at 301-436-1450 if you have questions concerning this petition.

Sincerely yours,

Michael A. Adams, Ph.D.
Acting Director
Division of Nutrition Science and Policy
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

02P 0457

ACK 1